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510(k) summary

JUL - 1 2011

This 510(k) Summary is being submitted in accordance with the requirement of SMDA 1990 and 21 CFR 807.92.

Sponsor:

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Date: May 25, 2011

Correspondent:

Contact person: Lynn Fu
Address: Building 11, Lishan Industrial Park, Xinghai Ave, Nanshan District, Shenzhen, Guangdong, 518052, China.

Proposed Device:

Trade Name: ANT Inflation Device/ ANT Inflation Device Compact Pack
Common Name: Angiographic injection/system
Classification Name: Balloon Inflation Device
Device Class: II
Regulation Number: 870.1650
Device Code: MAV

Predicate Device:

INDEFLATOR PLUS 30 Inflation Device and PLUS 30 PRIORITY PACK as cleared in K962495.

Intended Use:

The ANT Inflation Device is intended for use during vascular procedures in conjunction with interventional device such as balloon catheters to create and monitor pressure in the balloon catheter.

The ANT Inflation Device Compact Pack is a combination of the ANT Inflation Device and ANT Inflation Device Accessory Pack.

——ANT Inflation Device: See description above.

——ANT Inflation Device Accessory Pack: The Accessory Pack is recommended for use during vascular procedures in conjunction and/or

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diagnostic device (e.g., balloon dilatation catheters, arterectomy devices, sent delivery systems, intravascular ultrasound devices.)

Device Description:

ANT Inflation Device is a single-use, sterile device used in cardiovascular procedures to inflate and deflate balloon catheters. Pressure can be monitored via a pressure gauge. The manually operation of the device is achieved by the manipulation of a large handle to drive a piston housed within the body of the device. Careful and controlled inflation is achieved by rotating the handle clockwise. During inflation a unique cam locking mechanism maintains pressure up to 30 ATM.

ANT Inflation Device Accessory Compact Pack contains a hemostasis valve, a torque device, and a guide wire introducer. The hemostasis valve is designed to provide a port for interventional system. The guide wire introducer is used to facilitate placement of a guide wire tip through the hemostasis valve. The torque device is designed to hold the guide wire and provide a handle for manipulating.

Summary of the Studies

Performance test:

Accuracy of pressure gauge: Completely packaged devices are chose as the test samples. Filled them with water and connected to a calibrated pressure gauge, then pressurized to 3 settings, 4ATM, 16ATM, 27ATM, read the pressure and compared it to the calibrated gauge reading. This test showed the results comparable to other commercially device.

Leak test: Test samples were pressurized with water at 1ATM, 15ATM, 30ATM, and maintained 2 minutes. When immerse the samples into water, bubble occur indicate a leakage of the device. This test shows the connection of the device is comparable to other commercially device.

Competence test: attach the finished device to a legally marked catheter, and monitor the pressure during inflation and deflation. This test showed the results comparable to other commercially device.

Biocompatibility test:

ANT Inflation Device, when connected to a competent device such as a balloon catheter, is a closed system and does not delivery contrast or fluids to the circulation system. ANT Inflation Device Accessory Pack may contact the blood path indirectly as an external communicating device. Both of them meet the

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biocompatibility requirements of ISO 10993-1:2003.

Test Item	Standard
Vitro Cytotoxicity	ISO 10993-5
Delayed-type hypersensitivity	ISO 10993-10
irritation	ISO 10993-10
System toxicity	ISO 10993-11
Interactions with blood (Haemolysis test)	ISO 10993-4
Interactions with blood (Platelet adhesion)	ISO 10993-4
Interactions with blood (prothrombin time)	ISO 10993-4
Complement Activation Test	ISO 10993-4
In vitro Thrombogenicity	ISO 10993-4

Clinical Tests: Not Applicable

Substantial Equivalence:

Based on the intended use, summary of the studies, the subject device, ANT Inflation Device/ ANT Inflation Device Compact Pack, meet the requirements that are considered adequate for its intended use and is substantially equivalent to the INDEFLATOR PLUS 30 Inflation Device and PLUS 30 PRIORITY PACK.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Shenzhen ANT Hi-Tech Industrial Co., Ltd.
c/o Ms. Lynn Fu
Building 11, Lishan Industrial Park
Xinghai Ave., Nanshan District
Shenzhen, Guangdong
China 518052

JUL - 1 2011

Re: K102648
Trade/Device Name: ANT Inflation Device and ANT Inflation Device Compact Pack
Regulation Number: 21 CFR 870.1650
Regulation Name: Syringe, Balloon Inflation
Regulatory Class: Class II
Product Code: MAV
Dated: Not Dated
Received: June 23, 2011

Dear Ms. Fu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

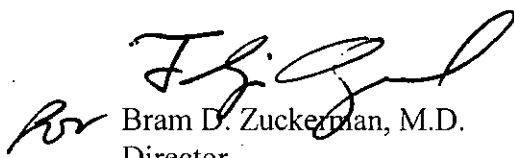
comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucml15809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number: K102648

Device Name: ATN Inflation Device
ANT Inflation Device Compact Pack

Indications for Use:

The ANT Inflation Device is intended for use during vascular procedures in conjunction with interventional device such as balloon catheters to create and monitor pressure in the balloon catheter.

The ANT Inflation Device Compact Pack:

—ANT Inflation Device: See description above.

—ANT Inflation Device Accessory Kit: The Accessory Kit is recommended for use during vascular procedures in conjunction and/or diagnostic device (e.g., balloon dilatation catheters, arterectomy devices, stent delivery systems, intravascular ultrasound devices.)


Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Cardiovascular Devices

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